AMENDMENT

Please amend the Claims as follows. An explanation of the changes to the Claims is found in the Remarks. Added text is underlined and deleted text is struck through.

IN THE CLAIMS:

1. (Currently Amended) An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric release region further comprising a polymer selected from the group consisting of homopolymers and copolymers containing polytetrafluoroethylene, collagen, cellulose, polyisobutylene, poly(2-methyl butane), and poly(2-methyl pentene) which comprise radiation sensitive groups, wherein said polymeric release region is treated with a radiation dose of at least 100,000 rads that is effective to (i) reduce the molecular weight of the polymer and (ii) substantially increase the cumulative release of said therapeutic agent in an amount of at least 10% subsequent to administration to a patient.

2. Cancelled.

3. (Original) The implantable or insertable medical device of claim 1, wherein said polymeric release region is treated with a radiation dose of at least 1,000,000 rads.

4. (Original) The implantable or insertable medical device of claim 1, wherein said polymeric release region is a carrier region that comprises said therapeutic agent.

5. (Original) The implantable or insertable medical device of claim 1, wherein said polymeric release region is a barrier region disposed over a therapeutic-agent-containing region that comprises said therapeutic agent.

6. (Original) The implantable or insertable medical device of claim 1, wherein said polymeric release region is in the form of a coating layer.

7. (Original) The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is selected from a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch, and a shunt.

8. (Original) The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is adapted for implantation or insertion into the coronary vasculature, peripheral vascular system, esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.

9. (Original) The implantable or insertable medical device of claim 1, wherein said therapeutic agent is selected from one or more of the group consisting of an anti-thrombotic agent, an anti-proliferative agent, an anti-inflammatory agent, an anti-migratory agent, an agent affecting extracellular matrix production and organization, an anti-neoplastic agent, an anti-mitotic agent, an anesthetic agent, an anti-coagulant, a vascular cell growth promoter, a vascular cell growth inhibitor, a cholesterol-lowering agent, a vasodilating agent, and an agent that interferes with endogenous vasoactive mechanisms.

10. (Currently Amended) The implantable or insertable medical device of claim 1, wherein the cumulative release of therapeutic agent is increased by an amount selected from 15% or more, 25% ~~,~~ or more, 35% or more, 50% or more, 100% or more, and 200% or more, 400% or more, or 1000% or more, after a period of administration selected from 1 day, 2 days, 4 days, 1 week, 2 weeks, 4 weeks, 2 months, 6 months and 1 year.

11. (Original) The implantable or insertable medical device of claim 1, wherein the cumulative release of therapeutic agent is increased by an amount ranging from 25% to 1000%, after a period of administration selected from 1 day, 2 days, 4 days, 1 week, 2 weeks, 4 weeks, 2 months, 6 months and 1 year.

12. (Original) The implantable or insertable medical device of claim 1, wherein said polymer comprises polyisobutylene, and wherein said cumulative release of therapeutic agent is increased

by an amount ranging from 25% to 1000% after a period of administration selected from 3.5 days, 1 week, and 2 weeks.

13. (Original) The implantable or insertable medical device of claim 1, wherein said polymer comprises polyisobutylene and polystyrene, and wherein said cumulative release of therapeutic agent is increased between 100% and 1000% after 1 week of administration.

14. Previously cancelled.

15. (Withdrawn) The implantable or insertable medical device of claim 1, wherein said polymer comprises poly(methyl methacrylate).

16. (Original) The implantable or insertable medical device of claim 1, wherein said polymer comprises polyisobutylene.

17. (Original) The implantable or insertable medical device of claim 16, wherein said polymer comprises polyisobutylene and polystyrene.

18. (Original) The implantable or insertable medical device of claim 17, wherein said polymer is a polystyrene-polyisobutylene-polystyrene triblock copolymer.

19. (Withdrawn) A method of forming the implantable or insertable medical device of claim 1, comprising: (a) applying a coating comprising said polymer on a surface of an implantable or insertable medical device; and (b) exposing said coating to a radiation dose that is effective to substantially increase the cumulative release of said therapeutic agent subsequent to administration to a patient.

20. (Withdrawn) The method of claim 19, wherein said radiation dose is at least 100,000 rads.

21. (Withdrawn) The method of claim 19, wherein said radiation dose is at least 1,000,000 rads.

22. (Withdrawn) The method of claim 19, wherein said radiation dose is provided by gamma ray or electron beam radiation.

23. (Withdrawn) The method of claim 19, wherein said coating is applied over a therapeutic-agent-containing region that comprises said therapeutic agent.

24. (Withdrawn) A method of releasing a therapeutic agent within a patient comprising (a) providing the implantable or insertable medical device of claim 1 and (b) implanting or inserting the implantable or insertable medical device into a patient.

25. (Withdrawn) The method of claim 24, wherein said medical device is selected from a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch, and a shunt.

26. (Withdrawn) The method of claim 25, wherein said medical device is inserted into the vasculature.

27. (Withdrawn) The method of claim 26, wherein said therapeutic agent is released in the treatment of restenosis.

28. (Withdrawn) A method for providing first and second implantable or insertable medical devices having first and second release profiles comprising: (a) providing first and second implantable or insertable medical devices comprising a therapeutic agent and a polymeric release region that further comprises a polymer, and (b) exposing said first medical device to a first radiation dose that is effective to provide a first substantial increase in the cumulative release of said therapeutic agent subsequent to administration to a patient, and (c) exposing said second medical device to a second radiation dose that is higher than said first dose to provide a second substantial increase in the cumulative release of said therapeutic agent subsequent to administration to a patient, wherein said second substantial increase is greater than said first substantial increase.

29. (Withdrawn) A method comprising: (a) identifying an implantable or insertable medical device for which increased release is desired, said implantable or insertable medical device comprising a therapeutic agent and a polymeric release region that further comprises a polymer, and (b) exposing said medical device to a radiation dose that is effective to provide a substantial increase in the cumulative release of said therapeutic agent subsequent to administration to a patient.

Please add new Claim 30:

30. (New) The implantable or insertable medical device of claim 3, wherein said polymeric release region is treated with a radiation dose in the range of 1 Mrad to 10 M rad.